**SUPHEDRINE PE- phenylephrine hcl tablet, film coated**
**GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Healthcare 44-453**

### *Active ingredient (in each tablet)*

Phenylephrine HCl 10 mg

### *Purpose*

Nasal decongestant

### *Uses*

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves sinus congestion and pressure

### *Warnings*

**Do not use**

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- diabetes
- heart disease
- high blood pressure
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland

**When using this product**

**do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with fever

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

***Directions***

- adults and children 12 years and over: take 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- children under 12 years: ask a doctor

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

***Inactive ingredients***

croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

***Questions or comments?***

**Call 1-800-426-9391**

**Principal Display Panel**

**HEALTHCARE™**

**NDC 64092-802-18**

*Compare to the active ingredient in Sudafed PE®  Congestion

Maximum Strength

**Suphedrine PE**
**Phenylephrine HCl 10 mg**
**Nasal Decongestant**

*Relieves:*
*• Nasal & Sinus Congestion due to Colds & Allergies*

Pseudoephedrine FREE

**Non-Drowsy**

**18 TABLETS**

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Sudafed PE® Congestion. 50844 REV0118G45344

Distributed by:
Great Lakes Wholesale
& Marketing L.L.C.
3729 Patterson Ave., S.E.
Grand Rapids, MI 49512
www.glwholesale.com

**HEALTHCARE GUARANTEE**
If you are not completely satisfied with this product, regardless of reason, return your unused portion to Great Lakes Wholesale for a full refund

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**


**Healthcare 44-453**

## SUPHEDRINE PE

phenylephrine hcl tablet, film coated

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:64092-802 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **DEXTROSE MONOHYDRATE** (UNII: LX22YL083G) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **TRISODIUM CITRATE DIHYDRATE** (UNII: B22547B95K) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **CARBOXYMETHYLCELLULOSE SODIUM** (UNII: K679OBS311) | |
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **LECITHIN, SOYBEAN** (UNII: 1DI56QDM62) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | red | **Score** | no score |
| **Shape** | ROUND | **Size** | 7mm |
| **Flavor** | | **Imprint Code** | 44;453 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:64092-802-18 | 1 in 1 CARTON | 01/14/2005 | |
| **1** | | 18 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 01/14/2005 | |

## Labeler - GREAT LAKES WHOLESALE, MARKETING, & SALES, INC. (361925498)

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 038154464 | pack(64092-802) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | manufacture(64092-802) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | pack(64092-802) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 868734088 | pack(64092-802) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 967626305 | pack(64092-802) |

Revised: 4/2021 GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.